REMARKS

The new claims recite the limitations of the canceled claims, except for claims 44-45, which find support at p.4, lines 11-14. These amendments do not add new matter.

ISSUE

I. THE PROPRIETY OF THE ACTION'S REJECTION OF THE CLAIMS UNDER THE WRITTEN DESCRIPTION REQUIREMENT OF 35USC112, FIRST PARAGRAPH.

ARGUMENT

I. THE ACTION'S REJECTION OF THE CLAIMS UNDER THE WRITTEN DESCRIPTION REQUIREMENT OF 35USC112, FIRST PARAGRAPH IS IMPROPER.

The claims require detecting the presence of or predisposition to an ectodermal disorder by (a) detecting the presence of a human TAJ gene or gene product in a cell of a host predetermined to be at elevated risk of having or being predisposed to a particular ectodermal disorder; and (b) correlating the presence of the TAJ gene or gene product with a presence of or predisposition to the ectodermal disorder, wherein the TAJ gene or gene product is a variant correlated with the presence of or predisposition to the ectodermal disorder, and wherein the detecting step comprises detecting a TAJ gene, TAJ gene transcript or a TAJ protein.

The Specification thoroughly teaches and exemplifies the method defined by these steps. For step (a), the Specification describes a variety of suitable detection methodologies (p.4, lines 9-28; p.6, lines 3-13), teaches a large panel of exemplary TAJ specific probes (allele-specific antibodies and hybridization probes; p.4, line 31 - p.6, line 2), and provides detailed exemplification of detection by in situ and chromosomal hybridization (p.9, lines 3-17), TAJ allele-specific PCR amplification (p.12, lines 5-22), transcriptional reporter assay (p.10, lines 6-29), and immunocytochemistry (p.14, line 29 - p.15, line 5); see also p.17, lines 14-31. Step (b) involves no more than correlating the detected TAJ gene or gene product with an ectodermal disorder. In many cases, this entails no more than cross-referencing to a known clinical correlate. The Specification describes alternative means to implement this step (p.6, lines 14-26), teaches a large panel of TAJ genes and gene products associated with an ectodermal

disorder (p.3, line 16 - p.4, line 3) and provides detailed exemplification of correlation by chromosomal mapping (p.9, lines 12-17), animal model (p.9, line 18 - p.10, line 3) and clinical diagnosis (p.12, lines 5-22).

We submit that the Action does not examine the claims at issue. The Action does not identify any step of the claimed method which is not fully described. First, the Action extracts from our claim the term "ectodermal disorders", and argues that there are many of them, yet the specification does not disclose what mutations correlate to particular disorders. Action, p.3, line 2 - p.4, line 2.

Our claims do not require that the practitioner know correlations of many ectodermal dysplasias with many TAJ mutations. The practitioner merely detects *a* TAJ mutant in a host predetermined to be at elevated risk of having or being predisposed to a particular ectodermal disorder, and then correlates *that* mutant to the presence of *that* ectodermal disorder. Whether the number and potential causes of ectodermal disorders are 5 or 500 is submitted to be not relevant to our claims. Note, for example, the exemplification shown in Example IV (p.12, lines 5-22). There is no comprehensive foreknowledge required – the cell comes from a particular source (e.g. patient) having a particular, required clinical presentation, to which the practitioner is not blind. In fact, the particular, required clinical presentation of ectodermal disease is the reason the patient's TAJ gene is being analyzed. The entire detection method is demonstrated in Example IV, wherein the practitioner detects the presence of the human TAJ gene product (by PCR) and correlates that presence with an ectodermal disorder (Clouston syndrome).

The two steps of the claimed methods are fully described. Examination must focus on the claims, and the Action has not shown that either step of the claimed method is not fully described.

Second, the Action examines a TAJ cDNA (Action, p.4, line 3 - p.6, line 4), citing rich legal authority on conception of a cDNA sequence, and then argues that the specification does not describe structural features common to a genus of TAJ variants that would impart the function of causing a particular ectodermal disorder. The Action dismisses the specification as an invitation to find TAJ mutations that might be correlated with an ectodermal disorder. Action, p.6, lines 5-13.

The Action's argument does not address the pending claims, which do not require the

practitioner to find any TAJ mutations that might be correlated with an ectodermal disorder. The invention is a two-step method, and the two steps are described and demonstrated. The Action does not and can not identify any step of the claimed method which is not fully described. The Action can and does identify a lot of caselaw dismissing claims to unidentified and undefined cDNA molecules. However, our claims to TAJ cDNAs are the subject of a different patent application (see, WO9911791) – not this one.

Though there is no evidence to the contrary, we have provided an expert Declaration under 37CFR1.132 (copy attached) documenting that the Specification indeed conveys possession of the claimed two-step detection method. In particular, Dr. Richard Gaynor avers, inter alia, that the human TAJ genes and corresponding gene products are known in the art (Specification, p.1, lines 21-22). Furthermore, the present specification expressly recites the nucleotide and amino acid sequences of the full-length human TAJ protein and its native coding sequence (SEQ ID NOS:2 and 1, respectively). Hence, the human TAJ gene or gene product subject to detection may be a mutation of the disclosed wild-type TAJ sequence (Specification p.3, line 16 - p. 4, line 3) and it is the disclosed wild-type sequences that are used to detect such mutants (Specification p.4, line 31 - p.6, line 2; p.7, line 21 - p.8, line 18; see also Examples IV, V and VI). Accordingly, in his expert opinion, the steps of the claimed method are clearly described in the specification to reasonably convey to one of ordinary skill in the art that the inventors, at the time the application was filed, had possession of the claimed invention, particularly the claimed methods for detecting a "human TAJ gene or gene product."

Furthermore, Dr. Gaynor avers that the Specification thoroughly teaches and exemplifies the method defined by the recited two steps. For step (a), the specification describes a variety of suitable detection methodologies (p.4, lines 9-28; p.6, lines 3-13), teaches a large panel of exemplary TAJ specific probes (allele-specific antibodies and hybridization probes; p.4, line 31 - p.6, line 2), and provides detailed exemplification of detection by in situ and chromosomal hybridization (p.9, lines 3-17), TAJ allele-specific PCR amplification (p.12, lines 5-22), transcriptional reporter assay (p.10, lines 6-29), and immunocytochemistry (p.14, line 29 - p.15, line 5); see also p.17, lines 14-31. Step (b) involves no more than correlating the detected TAJ gene or gene product with an ectodermal disorder. In many cases, this entails no more than cross-referencing to a known clinical correlate. The specification describes alternative means to

gene or gene product with an ectodermal disorder. In many cases, this entails no more than cross-referencing to a known clinical correlate. The specification describes alternative means to implement this step (p.6, lines 14-26) and teaches a large panel of TAJ genes and gene products associated with an ectodermal disorder (p.3, line 16 - p.4, line 3).

Accordingly, the uncontroverted evidence of record confirms that the Specification conveys to one skilled in the art possession of the invention as claimed. Absent countervailing evidence to the contrary, the claims are in compliance with 35USC112, first paragraph.

The Examiner is invited to call the undersigned if he would like to amend the claims to clarify the foregoing or seeks further clarification of the claim language.

We petition for and authorize charging our Deposit Account No.19-0750 all necessary extensions of time. The Commissioner is authorized to charge any fees or credit any overcharges relating to this communication to our Dep. Acct. No.19-0750 (UTSD:0680).

Respectfully submitted,
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encl. 132 Declaration (of record, 3 p.)